Via E-Mail to:
National.List@usda.gov

Omya Inc.
61 Main St.
Proctor, VT
05765

August 16, 2005

Arthur Neal, Director, Program Administration
National Organic Program
USDA-AMS-TMP-NOP
1400 Independence Avenue, SW
Room 4008-So. Bldg., Ag Stop 0268
Washington, D.C. 20250

RE: **Docket Number: TM-04-07**
USDA's Advance Notice of Proposed Rulemaking; 70 FR 35177
"National Organic Program, Sunset Review"

Dear Mr. Neal:

In the June 17, 2005 Federal Register (70 FR 35177), the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) published an advance notice of proposed rulemaking with request for comments in which it announced that it is seeking public comment to help it "... determine whether [certain] substances should continue to be allowed or prohibited in the production and handling of organic agricultural products".

One of those substances of interest, specifically included on the so-called National List at 7 CFR 205.605, is the food ingredient "Calcium Carbonate". Although not specifically listed, a closely-related and functionally-equivalent food ingredient, "Ground Limestone", is also of interest by virtue of a letter from Richard Mathews of the AMS dated October 3, 2003 stating that "Calcium Carbonate, as listed under 7 CFR 205.605, does include food grade ground limestone" (copy attached).

Omya's comments that follow support the continued allowance of Calcium Carbonate *"as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))"* as currently provided under 7 CFR 205.605. Furthermore, at the same time Omya would like to take this opportunity to request that the National Organic Program (NOP) formally add "Ground Limestone" to the National List, thereby eliminating the need for users of that important food ingredient to rely on the AMS letter cited above for regulatory 'coverage'.

Introduction

Omya is one of the world's leading suppliers of ground calcium carbonate to the paper, paint, and plastics industries. Omya operates approximately 150 production facilities in about forty countries worldwide, including eight in North America. One of our flagship plants and our North American corporate headquarters are located in Vermont.

Omya's North American production processes involve grinding quarried marble ore (geologically-speaking, "metamorphosed limestone") and classifying it to create distinct products defined by particle size distribution. In addition to producing ground calcium carbonate products used as mineral fillers and pigments by the paper, paint, and plastics industries, Omya's Arizona facility also produces food-grade products meeting Food Chemicals Codex (FCC) and U.S. Food and Drug Administration (FDA) Generally Recognized As Safe (GRAS) specifications for "Ground Limestone" (21 CFR 184.1409).

Points Of Clarification

Before addressing the reasons why Calcium Carbonate (and, indirectly, Ground Limestone) should be allowed to remain as approved ingredients in or on processed organic products, we would like to reiterate some of the reasons why the NOP previously determined that Ground Limestone is included/subsumed under the term "Calcium Carbonate" at 7 CFR 205.605(a)(3).

First, there is very little actual difference between these two GRAS food ingredients. Per FCC V monograph specifications, the primary difference is that Calcium Carbonate must have a minimum calcium carbonate content of 98%, whereas Ground Limestone must have a minimum calcium carbonate content of 94%. The other differences relate to the allowable amounts of non calcium carbonate minerals present, essentially accounting for the 4% calcium carbonate discrepancy which is attributed to their different production methods -- Calcium Carbonate being typically (although not exclusively) produced via chemical synthesis processes, and Ground Limestone being produced by the mechanical grinding of natural limestone and thus sometimes having slightly more 'other' mineral content.

Second, in the August 31, 1982 Federal Register notice of its Tentative Final Rule on "GRAS Status of Carbonates and Bicarbonates" (47 FR 38349), the FDA made the following response to a public comment regarding Ground Limestone:

> "*One comment requested that Ground Limestone be considered a GRAS form of Calcium Carbonate, because Ground Limestone is listed that way in the Food Chemicals Codex. Consequently ... the agency has added a provision (21 CFR 184.1409) that permits the use of Ground Limestone for the same uses as Calcium Carbonate, provided that the ingredient meets the specifications for Ground Limestone in the Food Chemicals Codex, and that it is labeled as such.*" (emphasis added).

Third, a letter from the FDA to Omya dated February 17, 1998 illustrated how food grade Ground Limestone was often overlooked, even by regulatory agencies, as a legitimate calcium-rich food ingredient. In that letter, the FDA acknowledged that it inadvertently omitted Ground Limestone from the list of approved calcium sources in its rule authorizing calcium and osteoporosis health claims, and then clarified that Ground Limestone is indeed so approved.

Fourth, in another letter from the FDA to Omya dated July 22, 1998, the FDA also agreed that "calcium carbonate" may be used as the "common or usual name", as defined in its regulation at 21 CFR 102.5, to describe Ground Limestone in the ingredient list of a finished food product. The FDA acknowledged that had been common practice in the food industry for what was then over two decades.

Fifth, from a philosophical perspective, Ground Limestone made more sense as an ingredient in organic foods than most Calcium Carbonates. Per its GRAS regulation at 21 CFR 184.1191, the FDA states that food grade Calcium Carbonate is "... *prepared by three common methods of manufacture: 1) as a byproduct in the lime soda process; 2) by precipitation of calcium carbonate from calcium hydroxide in the carbonation process; or 3) by precipitation of calcium carbonate from calcium chloride in the calcium chloride process*". In contrast to these chemical synthesis methods, food grade Ground Limestone is always produced by much simpler mechanical means. Per its GRAS regulation at 21 CFR 184.1409, the FDA states that Ground Limestone "... *is prepared by the crushing, grinding, and classifying of naturally occurring limestone*". For this reason, Ground Limestone is often referred to by the food industry as "natural calcium carbonate", reflecting on what would seem to be a better 'fit' with organic food products.

Principal Reasons in Support of Continued Allowance

The most common use of Calcium Carbonate/Ground Limestone in processed foods, organic and non-organic alike, is for calcium fortification. They are by far the most widely utilized calcium fortification sources, owing largely to their good digestive absorbtion and their relatively low cost compared to other calcium sources.

Decades ago health professionals first sounded the alarm that American diets are generally calcium-deficient. Fortunately, over time the food industry responded by fortifying many processed foods with calcium, primarily via calcium carbonate, ground limestone, or calcium citrate, which has helped many people significantly increase their calcium intakes. Yet osteoporosis persists as a major medical problem, often with debilitating and costly domino effects. Otherwise-minor falls by the osteoporotic elderly routinely result in broken bones, long hospital stays, premature nursing home admissions, reduced quality of life and longevity, and sky-high medical bills.

On October 14, 2004 the U.S. Surgeon General -- the nation's most prominent physician -- reiterated the calcium warning in "Bone Health and Osteoporosis: A Surgeon General's Report" (see http://www.surgeongeneral.gov/library/bonehealth/). A companion booklet for lay people, "What [The Report] Means to You", states, "Lack of calcium has been singled out as a major public health concern because it is critically important to bone health. The average American consumes far less than the amount recommended."

As identified by the Surgeon General, key risk factors for osteoporosis are insufficient calcium intake both during critical early-life bone-building years, and as resorptive bone loss occurs beginning typically in mid-life. Thus, those at risk of osteoporosis potentially includes large population segments with less-than-optimal diets -- in other words, an awful lot of people.

The USDA's own Agricultural Research Service (ARS), its chief scientific research arm, has sponsored considerable research confirming the importance of adequate dietary calcium -- and has helped spread the word. For example, it supported a study that resulted in the publication of a December 9, 2002 article by Alfred Flores titled "Calcium-Fortified Cereals Help Kids Meet Needs", which remains available on the ARS web site (see http://www.ars.usda.gov/is/pr/2002/021209.htm).

Thus it would make absolutely no sense, and in fact be contrary to the oft-stated goals of numerous government agencies and private health professionals, for the AMS to eliminate Calcium Carbonate/Ground Limestone from the National List. One might even say it would be irresponsible to take any action that would severely limit, if not completely eliminate, the use of such an important ingredient in an expanding segment of the food industry. In the case of Ground Limestone, it would also be quite ironic, as it is probably the most 'natural' of the various calcium fortification sources and thus the best 'fit' for use with processed organic foods.

Other Relevant Information in Support of Continued Allowance

As suggested in the Federal Register Notice, we considered the questions contained in the worksheet categories and evaluated the relevance to Calcium Carbonate/Ground Limestone's use as a food ingredient. While many questions did not apply, we would like to briefly comment on those that might. However, because Omya's production process is limited to the grinding of natural limestone, likewise our comments must be limited to that type of production process.

The production of food grade Ground Limestone results in minimal environmental contamination during production and use. Because it is produced as a dry powder, there is the potential for the creation of dust particles during production and end-use handling. However, any such dust is typically controlled using state-of-the-art fabric filters, from which collected material is returned to the process.

What little dust may escape is not harmful to the environment. In fact, it is likely beneficial. Ground limestone actually has several beneficial environmental uses, including application to agricultural soils as a pH modifier ('liming') and application to lakes and ponds acidified by modern precipitation also to control pH.

There is no potential for detrimental interaction with other materials used.

There are no adverse biological or chemical interactions in agro-ecosystems. As mentioned above, there are potential positive interactions in maintaining the health of soils and surface water sources.

There would be no detrimental physiological effects on soil organisms, crops, or livestock if there were to be contact. Again, there are potential positive interactions in maintaining soil health both as a pH modifier and as an essential plant nutrient (calcium). Furthermore, Ground Limestone may also be used for calcium fortification of animal feeds.

There are no toxic or other adverse actions of the material or its breakdown products in the environment.

There is no undesirable persistence or concentration of the material or breakdown products in the environment.

There are no harmful effects on human health. As described at length previously, calcium is an essential human nutrient of which most people don't ingest enough.

As described previously, food grade Ground Limestone is not formulated or produced by a chemical process, nor is it produced by a process that changes its chemical form as obtained from nature.

Conclusion

For the preceding reasons Omya strongly supports the continued allowance of Calcium Carbonate *"as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))"* as currently provided under 7 CFR 205.605. Again, Omya also encourages, and indeed requests, that the NOP formally add "Ground Limestone" to the National List, thereby eliminating the need for users of that important food ingredient to rely on the attached October 3, 2003 AMS letter for regulatory 'coverage'.

Omya appreciates the opportunity to submit information and comments on this important issue and hopes that they will be of substantial value to the AMS in its review process. We would like to remain an active participant in the process and would be happy to provide you with whatever additional information we can. Feel free to call me at (802) 770-7261 if we can be of further assistance.

Sincerely,
Omya Inc.

Neal W. Jordan
Manager of Environmental
& Regulatory Affairs

Attachment

United States Department of Agriculture
Agricultural Marketing Service
STOP 0268 – Room 4008-S
1400 Independence Avenue, SW.
Washington, D.C. 20250-0200

October 3, 2003

Mr. Neal W. Jordan
Manager of Environmental
& Regulatory Affairs
OMYA, Inc.
61 Main Street
Proctor, Vermont 05765

Dear Mr. Jordan:

Thank you for your letter dated, April 24, 2003, regarding Calcium Carbonate.

This correspondence confirms that limestone was considered by the National Organic Standards Board as a part of the review and recommendation for the use of Calcium Carbonate in organic food processing. Therefore, Calcium Carbonate, as listed under 7 CFR 205.605, does include food grade ground limestone.

Should you have any other questions, you may contact me at (202) 720–3252.

Thank you, again, for your inquiry.

Regards,

Richard H. Mathews
Program Manager
National Organic Program